AUG 2 5 2004

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[In Accordance with SMDA of 1990]

K040191

BiCONTACT Hip System

January 26, 2004

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 2916714

CONTACT: Joyce Kilroy
800/258-1946 x 5074 (phone)
610/791-6882 (fax)

TRADE NAME: BiCONTACT

COMMON NAME: BiCONTACT Hip System

DEVICE CLASS: Class II

PRODUCT CODE: LPH

CLASSIFICATION: 888.3358 – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented

REVIEW PANEL: Orthopedics

INDICATIONS FOR USE

The BiCONTACT Hip System (prosthesis, hip, semi-constrained, metal/polymer, porous uncemented) is intended to replace a hip joint.

The device is intended for:

- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

DEVICE DESCRIPTION

The BiCONTACT Hip Stem and Femoral Head are available in one design. The femoral stem is manufactured from Ti with a Ti plasma spray coating (Plasmapore). This component is intended for uncemented use. A CoCrMo femoral head is available. The acetabular cup is manufactured solely of UHMWPE.

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PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components", and
- "Draft Guidance for Femoral Stem Prostheses" was completed where applicable.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the new BICONTACT Hip Stem and Femoral Head is substantially equivalent in design to:

- 36mm V40 Femoral Head Components (K022077)
- Accolade TMZF Plus HA 127° Size Hip System (K023102)
- MAYO Conservative Hip Prosthesis (K030733)
- Smith & Nephew Hip System (K022902)
- Zimmer Anatomic (K041109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2004

Ms. Joyce Kilroy
Director, Regulatory Affairs
and Quality Assurance
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K040191
Trade/Device Name: BiContact Hip Stem and Femoral Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Prosthesis, Hip, semi-constrained, metal/polymer, porous uncemented
Regulatory Class: II
Product Code: LPH
Dated: August 12, 2004
Received: August 13, 2004

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

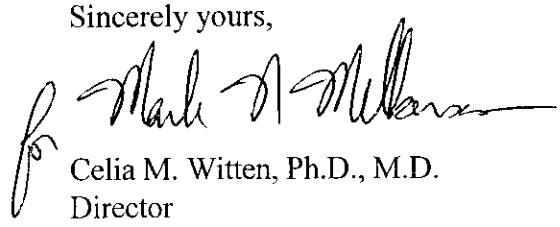
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K040191

Device Name: **BiCONTACT Hip System**

Indication for Use:

The BiCONTACT Hip System (prosthesis, hip, semi-constrained, metal/polymer, porous uncemented) is intended to replace a hip joint.

The device is intended for:

- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040191

Prescription Use X or Over-the-Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)